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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,409	01/18/2002	Susumu Maruo	Q68143	2146

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,409

Applicant(s)

MARUO ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2002 (paper no.3).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the IDS filed 04/19/02.

Claims 1-12 are pending. Claims 1-12 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-12 are indefinite because the term "applicator" is not clearly defined. The specification provides a vague definition/description of the term "applicator". Claim 8, lines 10-11 recite the phrase, "to adhere to skin with a part of the applicator". It is not clear what the applicant's are intending to claim. Example 5 on p.19, lines 8-9 recites "the sticky agent layer was used as the ointment applicator". Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda *et al.* (US Pat. No. 5, 045,553, collectively, "Ueda").

Ueda discloses a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount of 38.3 mg per cm² and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (see reference col. 7, lines 15-20 – Example 12). The gel patch preparation can further include an acrylic adhesive layer on the film (col. 7, lines 15-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda *et al.* (US Pat. No. 5, 045,553, collectively, "Ueda").

Ueda teaches a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount of 38.3 mg per cm² and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (see reference col. 7, lines 15-20 – Example 12). The gel patch preparation can further include an acrylic adhesive layer on the film (col. 7, lines 15-45). Ueda teaches that the pharmaceutical composition can be administered in various dosage forms. When the composition is in the form of a patch, the composition is spread over a support member (col. 3, lines 43-55). The composition may also be made up into ointments, such as Macrogol ointments, FAPG ointments, hydrophilic ointments, absorptive ointments, Carbopol gel ointments, etc (col. 3, lines 64-68). It is

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also possible to fill the composition in an appropriate container (to prevent adherence to clothes) and attach the container to the skin so that the composition can come into contact therewith or to coat a support member (as in tape preparations) with the composition to a certain thickness and apply the whole to the skin (col. 4, lines 9). Furthermore, the composition can be made up into patches, for example, by spreading the composition over an appropriate support member (i.e., made of aluminum), and if necessary sealing with an absorption promoter film such as ethylene-vinyl acetate copolymer film (col. 4, lines 10-20). The Examples on cols. 7-9 further demonstrate the use of patch preparations comprising a support member and a gel (ointment) in various percentages, which read on the applicant's instantly claimed ranges.

Ueda while teaching a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount of 38.3 mg per cm² and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (col. 7, lines 15-20 – Example 12), does not explicitly teach the degree of water vapor permeability of the support. It would have been deemed obvious to one of ordinary skill in the art at the time the invention was made and in the absence of showing the criticality of the instantly claimed vapor permeability range, suitable amounts or ranges of water vapor permeability could be determined through routine or manipulative experimentation.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
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